UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

PAUL HILLS,	)	
	)	
Plaintiff,	)	
	)	
	)	
v.	)	No. 1:08-cv-3329
	)	
BAXTER HEALTHCARE CORP.,	)	Judge Joan H. Lefkow
BAXTER INTERNATIONAL INC. and	)	
WYETH SUBSIDIARY ILLINOIS	)	
CORPORATION F/K/A SCIENTIFIC	)	
PROTEIN LABORATORIES,	)	
	)	
Defendants.	)	

Defendants' Response to Motion to Remand[1]

This Court need not and should not decide Plaintiff's motion to remand. The JPML has consolidated heparin-related actions into a multidistrict litigation ("MDL"), transferred the MDL proceeding to the Northern District of Ohio, and issued a conditional transfer order for this action. Thus, the most sensible course is to await transfer of this action and allow the MDL court to decide all issues of federal jurisdiction at once. Indeed, Chief Judge Holderman recently decided to do just that in a related heparin case.

In the event that the Court reaches the merits of Plaintiff's remand motion, it should retain jurisdiction. The Supreme Court's decision in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005) ("*Grable*") makes clear that Plaintiff need not assert a federal cause of action for federal question jurisdiction to apply. Here,

[1] "Defendants" herein includes Baxter Healthcare Corp. and Baxter International Inc. The other defendant, Wyeth Subsidiary Illinois Corporation f/k/a Scientific Protein Laboratories, had not been served as of removal (but nonetheless consented to the removal).

substantial and disputed federal questions are apparent from the face of Plaintiff's complaint – despite Plaintiff's attempt to downplay the role federal law will play.

Plaintiff asks this Court to find Defendants negligent for purportedly failing to comply with FDA approval and inspection requirements for foreign suppliers. Plaintiff also challenges Defendants' conduct in the very areas in which Defendants were governed by ***and complied with*** specific FDA requirements: manufacture; quality control; warnings; importation and procurement of biomedical products; inspection and approval of foreign suppliers; testing; and recall. Although framed in the language of state tort law, Plaintiff's claims directly challenge the FDA's approval and regulation of heparin and the federal regulatory process governing the approval and sale of prescription drugs. Accordingly, federal jurisdiction over Plaintiff's claims is proper and Plaintiff's motion to remand should be denied.

ARGUMENT

I. This Court Should Not Address Remand Issues, As The MDL Court Can And Should Decide Issues Related To Federal Jurisdiction In One Proceeding.

The allegations in this case substantially overlap with similar ones made in several other lawsuits filed throughout the United States. These cases have now been consolidated into an MDL proceeding and the MDL has been transferred to Chief Judge Carr in the Northern District of Ohio. (Ex. A) Defendants have notified the panel of this case as a tag-along action for transfer to the MDL, and the MDL panel has issued a conditional transfer order. (Ex. B) Accordingly, transfer of this case is both likely and imminent.

There are at least four other heparin cases that have been removed to federal court based, at least in part, on federal question jurisdiction. All federal jurisdictional issues can and should be handled in a single MDL proceeding to facilitate judicial economy and avoid inconsistent rulings – which are precisely the reasons for establishing the MDL. *See, e.g., Johnson v. AMR*

Corp., Nos. 95 C 7659 to 95 C 7664, 1996 WL 164415, at *4 (N.D. Ill. Apr. 3, 1996) (staying proceedings pending ruling by MDL panel on consolidation despite pending motion to remand and noting that MDL court should decide jurisdictional issues).

Other courts in removed heparin cases have decided to stay proceedings despite pending motions to remand to allow the MDL court to decide issues of federal jurisdiction. In *Arnold v. Baxter Healthcare Corp.*, No. 08-cv-2168 (N.D. Ill.), Chief Judge Holderman granted Baxter Healthcare Corp.'s motion to stay proceedings pending transfer to the MDL and declined to rule on plaintiff's fully briefed remand motion. The Court followed the three-part procedure set forth in *Meyers v. Bayer AG*, 143 F. Supp. 2d 1044, 1048-49 (E.D. Wis. 2001): (1) make a preliminary determination on the merits of the motion to remand; (2) if the jurisdictional question is difficult, "determine whether identical or similar jurisdictional issues have been raised in other cases that have been or may be transferred to the MDL proceeding"; and (3) if a difficult jurisdictional question is shared by other cases in the MDL proceeding, consider staying proceedings so the jurisdictional questions can be resolved together by the MDL court. (*See* Ex. C, 7/1/08 Order) Applying this analysis, the Court found stay appropriate:

> In this case, it appears that the FDA was heavily involved in approving the manufacturing, distribution, and sale of heparin. If Baxter in fact complied with all federal regulations, but was still found negligent under Illinois state law, this finding would necessarily implicate both the actions of the FDA and the efficacy of the applicable FDCA regulations. With these aspects of the case in mind, the court finds the jurisdictional question at issue to be fairly complex. . . . Because the jurisdictional question in this case warrants a careful analysis of the "congressionally approved balance of federal and state judicial responsibilities," *Grable*, 545 U.S. at 314, this court declines to rule on Plaintiffs' Motion to Remand at this time, deferring a determination on the merits so that the MDL court can uniformly treat this question in all similar cases pending before it.

(*Id.* at 3; *see also* Ex. D, 5/7/08 Order in *Fowler v. Hamilton Medical Center*, No. 4:08-cv-0055-HLM (N.D. Ga.) ("Additionally, the transferee court may well be in a better position to address the other motions that remain pending in this case, such as the Joint Motion to Remand. Under those circumstances, granting a stay will conserve judicial resources."))[2]

No court in a removed heparin case has ruled in favor of remand, nor do any appear poised to do so.[3] Here too, the better course would be to allow the MDL court to decide all issues of federal jurisdiction.

II. Federal Jurisdiction Is Proper In This Case, Which Raises A Host Of Federal Questions Related To Nearly Every Aspect Of The FDA's Regulatory Scheme.

Although Plaintiff's complaint masquerades as an ordinary state-law tort action, it squarely challenges determinations made by the FDA and the adequacy of federal requirements governing the manufacture and sale of prescription drugs. Resolving the allegations in this lawsuit will require a determination that specific aspects of the federal regulatory process governing prescription drugs are insufficient to protect the public health – a determination that clearly involves a substantial question of federal law.

A. Federal Jurisdiction Arises Where The Plaintiff's Claim Requires Resolution Of A Substantial Federal Question.

Although Plaintiff concedes that "a federal law may be applicable in the[se] proceedings" (Mem. at 5), Plaintiff contends that he can avoid federal jurisdiction by asserting a state law

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[2] The *Fowler* plaintiff later moved for voluntary dismissal and the case has been dismissed. Thus, Defendants' reference to four other cases removed on the basis of federal question jurisdiction does not include *Fowler*.

[3] Judge Gettleman, for instance, entered orders transferring cases pending before him to the MDL court despite a pending, fully briefed motion to remand in one case. (Ex. E, 6/23/08 Order in *Scott v. Baxter International Inc.*, No. 08-cv-02058-RWG (N.D. Ill.))

cause of action that is purportedly not "based on" violations of federal law. (*Id.* at 2) But the exercise of federal jurisdiction is both appropriate and warranted where the real nature of a plaintiff's claim is federal, irrespective of how the plaintiff has tried to characterize his claim. *See, e.g., Jones v. Gen. Tire & Rubber Co.*, 541 F.2d 660 (7th Cir. 1976).

The Supreme Court and other federal courts have readily recognized the existence of federal jurisdiction over claims that, while not created by federal law, nonetheless involve substantial questions of federal law necessary to the plaintiff's right to relief. *See, e.g., City of Chicago v. Int'l Coll. of Surgeons*, 522 U.S. 156, 164 (1997); *Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 27-28 (1983); *Smith v. Kan. City Title & Trust Co.*, 255 U.S. 180 (1921). While "the mere presence of a federal issue in a state cause of action does not automatically confer federal-question jurisdiction," it is axiomatic that certain cases depend on the resolution of a federal question sufficiently substantial to arise under federal law. *Merrell Dow Pharms. Inc. v. Thompson*, 478 U.S. 804, 813 (1986) ("*Merrell Dow*"); *see also Ormet Corp. v. Ohio Power Co.*, 98 F.3d 799, 807 (4th Cir. 1996) (same).

In 2005, the Supreme Court reaffirmed the substantial federal question doctrine in *Grable*. After the IRS seized Grable's real property and sold it to satisfy a federal tax delinquency, Grable brought a quiet title action in state court claiming that record title was invalid because the IRS had failed to properly notify Grable of the seizure. The defendant removed the case to federal court as presenting a federal question, because the state claim of title depended on the interpretation of the notice statute in the federal tax law. The Supreme Court granted certiorari to resolve a split within the Courts of Appeals on whether *Merrell Dow* always requires a federal cause of action as a condition for exercising federal-question jurisdiction.

The Court held that a federal cause of action was not required – "th[e] Court having recognized for nearly 100 years that in certain cases federal question jurisdiction will lie over state-law claims that implicate significant federal issues." 545 U.S. at 312. The Court explained:

> The [substantial federal question] doctrine captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues . . . .

Id. The Court determined that the meaning of the federal tax provision is an important issue of federal law that sensibly belongs in a federal court since the Government has a strong interest in the "'prompt and certain collection of delinquent taxes,' and the ability of the IRS to satisfy its claims from the property of delinquents requires clear terms of notice." *Id.* at 315 (citation omitted). "The Government thus has a direct interest in the availability of a federal forum to vindicate its own administrative action," and the other parties "may find it valuable to come before judges used to federal tax matters." *Id.*

Pursuant to *Grable*, federal question jurisdiction is proper where a state-law claim "necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Id.* at 321.

B. A Complex Federal Regulatory Scheme For Prescription Drugs Is Set Forth In The Food, Drug, And Cosmetic Act And Accompanying Regulations.

The Federal Food, Drug, and Cosmetic Act ("FDCA") was enacted by the United States Congress pursuant to the power conferred upon it under the Constitution to regulate interstate commerce. 21 U.S.C. §§ 301 *et seq.* The Act's overriding purpose as well as its primary objective is the protection of the public health; the Act is designed primarily to protect

consumers from dangerous products. *U.S. v. Bacto-Unidisk*, 394 U.S. 784 (1969); *U.S. v. Undetermined No. of Unlabeled Cases*, 21 F.3d 1026 (10th Cir. 1994); *Gen. Med. Co. v. U.S. Food & Drug Admin.*, 770 F.2d 214 (D.C. Cir. 1985). The Act is designed to protect public health by regulating certain products moving in interstate commerce. *U.S. v. Vital Health Prods., Ltd.*, 786 F. Supp. 761 (E.D. Wis. 1992), *aff'd*, 985 F.2d 563 (7th Cir. 1993). In this regard, the Act's main purpose is to prohibit the movement in interstate commerce of adulterated and misbranded drugs, devices, and cosmetics. *State v. Deputy*, 644 A.2d 411 (Del. Super. Ct. 1994). Furthermore, one of the Act's primary purposes is to ensure the safety of food and drugs before they become available to the public. *Vital Health Prods., Ltd.*, 786 F. Supp. 761.

The FDA approved Baxter's heparin products only after applying the comprehensive standards set forth in the FDCA and its accompanying regulations. The FDA approval process for new drugs is comprehensive. Applicants must submit, among other things, "full reports of investigations which have been made to show whether or not [the] drug is safe for use and whether [the] drug is effective in use." 21 U.S.C. § 355(b)(1). The formal approval process begins with the manufacturer's submission of an Investigational New Drug application ("IND") to conduct clinical trials. 21 C.F.R. § 312.20. Before filing the IND, the applicant must have subjected biologically active agents of the proposed drug to comprehensive animal and human tissue testing. 21 C.F.R. § 312.23(a). The applicant may commence human clinical trials if the FDA does not request more information or seek modifications to the testing protocols. 21 C.F.R. §§ 312.21-23, 312.40(b)(I). During the next stage of the approval process there are three phases of clinical trials. 21 C.F.R. § 312.21(a)(1), (b), & (c). By statute, the studies conducted must be "adequate and well-controlled." 21 U.S.C. § 355(d); *see* 21 C.F.R. § 314.126(b)(1)-(7). In reviewing the studies, the FDA conducts "an assessment of the scientific

quality of the clinical investigations." 21 C.F.R. § 312.22(a). Moreover, the FDA may require additional testing or studies at any stage in the approval process. 21 C.F.R. § 312.4l(a). Throughout, the FDA "monitor[s] the progress of the conduct and evaluation of clinical trials" and is "involved in facilitating their appropriate progress." 21 C.F.R. § 312.87.

After the successful completion of this testing regime, the applicant must submit a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a)-(d); 21 C.F.R. § 314.50. The NDA catalogues the history of the drug's development and testing. In seeking approval, the applicant must provide "substantial evidence" that the drug is safe and effective. 21 C.F.R. § 314.125(b)(5). This means:

> evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed.

21 U.S.C. § 355(d); *see also* 21 C.F.R. § 314.125(b).

In reviewing the scientific evidence regarding a proposed drug, the FDA is required to "establish panels of experts" consisting of "members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacturer, or utilization of such drugs." 21 U.S.C. § 355(n)(1) & (n)(3)(A). In determining whether a drug should be approved, the "FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards." 21 C.F.R. § 314.l05(c).

Significantly, the FDA is barred from approving a drug if it finds the manufacturing process deficient. The FDA "shall issue an order refusing to approve the application" if, among other things, "the methods used in, and the facilities and controls used for, the manufacture,

processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity." 21 U.S.C. § 355(d). Furthermore, FDA regulations set forth good manufacturing practices with which drug manufacturers must comply. *See, e.g.*, 21 C.F.R. § 211.1 ("regulations in this part contain the minimum current good manufacturing practice for preparation of drug products for administration to humans or animals").

The FDCA specifically defines when a drug is adulterated. Pursuant to 21 U.S.C. § 351, a drug is "adulterated," *inter alia*:

> (a)(1)(B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or. . . .
>
> (b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made.

The FDCA prohibits the introduction or sale of adulterated drugs into interstate commerce. 21 U.S.C. § 331. Among other things, the FDA has the authority to seize adulterated drugs that are introduced into interstate commerce. 21 U.S.C. § 334.

Even after approving a prescription drug, the FDA continues to evaluate its safety and efficacy. By law, manufacturers must report to the FDA "[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related." 21 C.F.R. § 314.80(a).

Prompt report of serious and unexpected adverse drug experiences is required, as is any increase in frequency of a particular adverse event. 21 C.F.R. § 314.80(c)(1). Moreover, the FDA, after due notice and opportunity for hearing to the applicant, is statutorily required to withdraw approval under specified circumstances. 21 U.S.C. § 355(e); *see also* 21 C.F.R. § 314.150.

The FDCA sets forth requirements for drug imports (including for components of drugs). *See, e.g.*, 21 U.S.C. § 381(a) ("The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of . . . drugs . . . which are being imported or offered for import into the United States . . . . If it appears from the examination of such samples or otherwise that . . . such article is adulterated . . . then such article shall be refused admission . . . ."). The FDCA gives the FDA authority to issue regulations, conduct examinations and investigations, request records of interstate shipments, conduct factory inspections, and so forth. 21 U.S.C. § 371 *et seq*.

The FDCA also closely regulates what information may and may not be disseminated by manufacturers. *See, e.g.*, 21 U.S.C. § 360aaa. Provision is made for the dissemination of information regarding drugs "in situations involving, in the opinion of the Secretary, imminent danger to [the] health or gross deception of the consumer." 21 U.S.C. § 375(b).[4]

C. Plaintiff's Claims Necessarily Raise Substantial And Disputed Questions Of Federal Law By Asking The Court To Interpret These Federal Requirements And Challenging The Federal Regulatory Scheme For Prescription Drugs.

Plaintiff alleges that defendants are liable "under theories of strict liability and negligence for designing, manufacturing, and distributing contaminated Heparin." (Mem. at 2) Plaintiff's

[4] Federal courts are currently split on the scope of preemption by the FDCA, *see, e.g., Colacicco v. Apotex Inc.*, 521 F.3d 253 (3d Cir. 2008) (finding preemption of failure to warn claim); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. M:05-1699 CRB, 2006 WL 2374742 (N.D. Cal. Aug. 16, 2006) (same); with the Supreme Court set to clarify the issue in its next term in *Wyeth v. Levine*, an appeal from the Supreme Court of Vermont. The FDA has set forth its view that the FDCA preempts at least labeling/warning claims. 71 Fed. Reg. 3933-35 (Jan. 24, 2006).

complaint alleges that Defendants are liable due to their purported conduct in the areas of design and manufacture, representations and warnings, procurement and importation of components, adverse event monitoring, recall, and testing. (*See* Compl. Counts I-IV, ¶¶ 11-47)

Plaintiff specifically asserts in his complaint that Defendants were negligent in procuring "the component parts for the multiple-dose heparin" from a plant in China when its facilities and operations had not "met the requisite requirements for importation and/or sale within the United States," including "inspection and approval by the Food and Drug Administration as is required for any facility to supply drug ingredients to the United States." (Compl. Counts I-IV, ¶¶ 23-27; *see also id.* ¶ 43) Plaintiff's assertions in this regard will require the Court to apply federal law to decide what the federal statute and regulations require and whether inspection and approval requirements were met. In addition, Plaintiff's claims are predicated on an allegation that the heparin was "contaminated." (*See* Mem. at 2; Compl. Counts I-IV, ¶¶ 11-47 (entitled "Contaminated Heparin")) That also requires the Court to decide a substantial, disputed issue of federal law. *See, e.g.*, 21 U.S.C. § 351 (defining when a drug is "adulterated").

Furthermore, Plaintiff's claims directly challenge the adequacy of numerous, specific aspects of the federal regulatory scheme with which Defendants complied, including, *inter alia*, (1) good manufacturing requirements; (2) warning and labeling requirements; (3) requirements for import of pharmaceutical products; (4) definitions and rules related to "adulterated" drugs; (5) testing requirements; (6) new drug approvals; and (7) adverse event report monitoring. The adequacy of Defendants' compliance with these federal requirements (and, in turn, the adequacy of the requirements themselves) are actually disputed, since Plaintiff's claims are premised upon the position that he can prevail on state law tort claims despite Defendants' compliance with

these aspects of the federal regulatory scheme. Moreover, these issues are substantial; indeed, they are at the heart of Plaintiff's complaint.

What is more, Plaintiff's claims expressly challenge the FDA's determinations related to heparin, including its approval of heparin and failure to withdraw approval, as well as its decisions on inspection and approval of the facility that supplied heparin components. In short, Plaintiff's claims are inextricably intertwined with the comprehensive federal scheme governing prescription drug approval. Because Plaintiff's claims cannot be decided without the judge or jury second-guessing FDA decisions and assessing the adequacy of the statute and regulations under which the FDA acted, those claims raise a substantial federal question.

The cases cited by Plaintiff do not warrant a different result.[5] *Higbee v. Malleris*, 470 F. Supp. 2d 845 (N.D. Ill. 2007) was a professional malpractice case that turned on whether counsel exercised "a reasonable degree of care and skill" as defined by Illinois law in handling her federal discrimination case (including whether preparations were adequate and so forth) – not anything in Title VII or the ADEA. *Sercye-McCollum v. Ravenswood Hosp. Med. Ctr.*, 140 F. Supp. 2d 944 (N.D. Ill. 2001), involved medical negligence claims. Although plaintiffs alleged

[5] Two cases not cited by Plaintiff also do not alter the result. *Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677 (2006) adhered to *Grable* but reached a contrary result given a different set of facts. *Empire* involved whether federal jurisdiction existed over a reimbursement claim arising from settlement of a state lawsuit and bears no factual similarity to the case at hand. In light of the nature of the federal interest at stake and the degree to which it is implicated, this case is far more akin to the circumstances in *Grable*. *Bennett v. Southwest Airlines Co.*, 484 F.3d 907 (7th Cir. 2007), which rejected the sweeping proposition that all product liability suits involving commercial air travel belong in federal court because federal aviation standards sometimes play a role, is likewise distinguishable. *See id.* at 909. Critically, plaintiffs in *Bennett* did not challenge the validity of any specific action by a federal agency, and the Seventh Circuit specifically noted that if the validity of the agency's actions were at stake, it would have reached a different result. *Id.* The removing defendants in *Bennett* did not point to any particular disputed issue of federal law. In addition, unlike in this case, the need for uniformity was not of great concern. *Id.* at 911 ("How flights proceed while airborne, and which safety devices an airframe should carry, may well be subjects on which only one national rule is tolerable. Many other subjects, however, vary from airport to airport.").

that defendants violated a federal statute in support of their claims, they had other unrelated theories – including six alleged violations of the Illinois Administrative Code.[6]

Merrell Dow addressed whether the need to apply a misbranding provision of the FDCA to resolve one count was sufficient to invoke substantial question jurisdiction over the entire six-count complaint. The Court did not address whether federal jurisdiction would exist over a case challenging the adequacy of any FDCA provision, much less myriad specific aspects of the FDCA's regulatory scheme. Moreover, concerning *Merrell Dow*, the *Grable* court noted:

> *Merrell Dow* cannot be read whole as overturning decades of precedent, as it would have done by . . . converting a federal cause of action from a sufficient condition for federal-question jurisdiction INTO A NECESSARY ONE . . . . In the first place, *Merrell Dow* disclaimed the adoption of any bright-line rule, as when the Court reiterated that "in exploring the outer reaches of § 1331, determinations about federal jurisdiction require sensitive judgments about congressional intent, judicial power, and the federal system." 478 U.S. at 810. . . .

545 U.S. at 317.[7]

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[6] *Rubel v. Pfizer Inc.*, 276 F. Supp. 2d 904 (N.D. Ill. 2003) (cited by Plaintiff), was decided pre-*Grable* and is predicated on *Merrell Dow*'s now-repudiated view that a federal cause of action is a necessary condition for substantial federal question jurisdiction.

[7] Post-*Grable* (and *Empire*), courts have found substantial federal question jurisdiction over state law claims in a variety of circumstances. *E.g., Nicodemus v. Union Pac. Corp*., 440 F.3d 1227 (10th Cir. 2006) (landowners' claims for trespass, unjust enrichment, and slander of title hinged on whether use of rights-of-way granted pursuant to federal land-grant statutes exceeded purpose for which they were granted and thus raised disputed issues of federal law); *In re Nat'l Sec. Agency Telecomm. Records Litig.*, 483 F. Supp. 2d 934 (N.D. Cal. 2007) (state-law privacy claims against telephone companies for alleged release of calling records to National Security Agency gave rise to federal question jurisdiction where application of state secrets doctrine presented disputed and substantial question); *Adventure Outdoors, Inc. v. Bloomberg*, 519 F. Supp. 2d 1258 (N.D. Ga. 2007) (removal proper where court had to determine whether gun brokers' sales to investigators violated federal law to decide brokers' negligence and defamation claims); *In re Pharm. Indus. Average Wholesale Price Litig*., 457 F. Supp. 2d 77, 81 (D. Mass. 2006) (interpretation of "average wholesale price" provision of federal Medicare statute raises substantial federal question).

D. The Federal Courts Can And Should Exercise Jurisdiction In This Case Without Disturbing Any Congressionally Approved Balance Of Federal And State Judicial Responsibilities.

Key factors for determining whether federal jurisdiction will be imposed include the importance of the federal interest at stake and whether the exercise of federal jurisdiction will result in a flood of new federal cases. *See Grable*, 545 U.S. at 321; *see also Ormet Corp.*, 98 F.3d at 806-07 (determination "should be informed by a sensitive judgment about whether the existence of federal judicial power is both appropriate and pragmatic"; "[w]here the resolution of a federal issue in a state-law cause of action could, because of different approaches and inconsistency, undermine the stability and efficiency of a federal statutory regime, the need for uniformity becomes a substantial federal interest . . . .").

Here, the need for uniformity is compelling, because Plaintiff's lawsuit raises the potential for disparate requirements for the approval, manufacture and sale of prescription drugs, imposed by courts throughout the country, that could both conflict with and undermine the regulatory framework designed to provide a uniform standard for assuring the safety and efficacy of prescription drugs. Indeed, the federal interests at stake, including the need for uniformity, are particularly compelling here given the centrality of the allegations in the complaint that prescription drug components were adulterated and imported from a foreign facility that was not properly FDA-inspected and approved. (*See* Compl. Counts I & III, ¶¶ 23-27 & 43) The need for standard and uniform federal requirements relating to importation from and inspection of foreign facilities is a critical federal interest. *See S.-Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 96 (1984) (a higher level of scrutiny is required for state actions restraining foreign commerce because, unlike interstate commerce, the United States must speak with a single voice for effective relations and trade with foreign nations); *Japan Line, Ltd. v. County of Los Angeles*, 441 U.S. 434, 448 (1979) ("[f]oreign commerce is pre-eminently a matter of national concern").

At bottom, the centrality and sensitivity of these federal issues distinguish this case from product liability actions that only peripherally raise federal issues, including federal standards.

Moreover, Plaintiff is wrong that the floodgates will open from the exercise of jurisdiction under the circumstances. (*See* Mem. at 3) Defendants do not seek a ruling that all state law product liability claims that implicate federal standards – no matter how indirectly – are subject to federal jurisdiction. Defendants simply seek a ruling that, pursuant to the sensitive, case-by-case inquiry required by the Supreme Court's decisions, federal jurisdiction is appropriate here given the significant scope and nature of Plaintiff's challenges to federal requirements and determinations.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court refrain from ruling on Plaintiff's motion to remand or, in the alternative, that the Court deny the motion.

This the 10th Day of July, 2008.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 10, 2008, I electronically filed Defendants' Response to Motion to Remand with the Clerk of the Court using the CM/ECF System which will send notification of such filing to registered E-filers and mailed, by United States Postal Service, the document to the following:

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EXHIBIT A

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: HEPARIN PRODUCTS LIABILITY LITIGATION MDL No. 1953

TRANSFER ORDER

Before the entire Panel: Plaintiff in the Southern District of Florida action moves, pursuant to 28 U.S.C. § 1407, for coordinated or consolidated pretrial proceedings of this litigation. No responding party opposes centralization, but there is disagreement over the selection of a transferee forum. Movant and responding plaintiffs suggest centralization in the districts in which their actions are pending – the Southern District of Florida, the Northern District of Ohio or the District of Puerto Rico; at the Panel hearing session, movant also proffered the Northern District of California. Defendants[1] prefer selection of either the Northern District of Illinois or the District of New Jersey; also, defendants stated during oral argument before us that they do not object to centralization in the Northern District of Ohio. Plaintiffs in various potential tag-along actions either support one of these districts or suggest the Western District of Pennsylvania or the Western District of Wisconsin. The latter is the alternative choice of plaintiff in the District of Puerto Rico action included in the motion. Plaintiffs in one potential tag-along action pending in the District of New Jersey do not advocate centralization in a specific district, but urge the Panel to select a transferee district which can undertake active management of these proceedings on a priority basis.

This litigation presently consists of three actions listed on Schedule A and pending in three districts as follows: one action each in the Southern District of Florida, the Northern District of Ohio, and the District of Puerto Rico.[2]

On the basis of the papers filed and hearing session held, we find that the actions in this litigation

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[1] Baxter Healthcare Corp., Baxter International, Inc., and Baxter Healthcare Corp. of Puerto Rico (collectively Baxter); and Scientific Protein Laboratories, LLC.

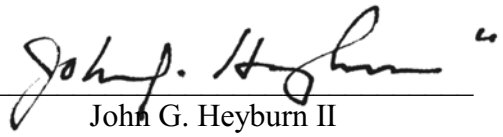
[2] The Panel has been notified that twenty other related actions have recently been filed, six actions in the Northern District of Ohio, four actions in the Northern District of Illinois, two actions each in the District of New Jersey and the District of Puerto Rico, and one action each in the Middle District of Florida, the Northern District of Georgia, the Eastern District of Louisiana, the Eastern District of Tennessee, the Eastern District of Texas and the Western District of Pennsylvania. These actions will be treated as potential tag-along actions. *See* Rules 7.4 and 7.5, R.P.J.P.M.L., 199 F.R.D. 425, 435-36 (2001).

involve common questions of fact, and that centralization under Section 1407 in the Northern District of Ohio will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation. All actions share factual questions relating to the manufacture and sale by Baxter of allegedly adulterated Heparin causing economic or personal injuries; this Heparin was recalled in February 2008. Centralization under Section 1407 will eliminate duplicative discovery; avoid inconsistent pretrial rulings; and conserve the resources of the parties, their counsel and the judiciary.

We are persuaded that the Northern District of Ohio is an appropriate transferee district for this litigation. Seven of the 23 known actions are pending in this district mostly before Judge James G. Carr who has the time to devote to this docket.

IT IS THEREFORE ORDERED that, pursuant to 28 U.S.C. § 1407, the actions listed on Schedule A and pending outside the Northern District of Ohio are transferred to the Northern District of Ohio and, with the consent of that court, assigned to the Honorable James G. Carr for coordinated or consolidated pretrial proceedings with the action pending there and listed on Schedule A.

PANEL ON MULTIDISTRICT LITIGATION



John G. Heyburn II
Chairman

D. Lowell Jensen
Robert L. Miller, Jr.
David R. Hansen
J. Frederick Motz
Kathryn H. Vratil
Anthony J. Scirica

IN RE: HEPARIN PRODUCTS LIABILITY LITIGATION MDL No. 1953

SCHEDULE A

Southern District of Florida

David D'Amico v. Baxter Healthcare Corp., et al., C.A. No. 9:08-80311

Northern District of Ohio

Leroy Hubley, etc. v. Baxter Healthcare Corp., et al., C.A. No. 3:08-377

District of Puerto Rico

Esther S. Rivera v. Baxter International, Inc., et al., C.A. No. 3:08-1368

EXHIBIT B

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

DIRECT REPLY TO:

Jeffery N. Lüthi
Clerk of the Panel
One Columbus Circle, NE
Thurgood Marshall Federal
Judiciary Building
Room G-255, North Lobby
Washington, D.C. 20002

Telephone: [202] 502-2800
Fax: [202] 502-2888
http://www.jpml.uscourts.gov

July 3, 2008

TO INVOLVED COUNSEL

Re: MDL No. 1953-- IN RE: Heparin Products Liability Litigation

(See Attached CTO-2)

Dear Counsel:

Attached hereto is a copy of a conditional transfer order filed today by the Panel involving the above-captioned matter. This matter is transferred pursuant to Rule 7.4 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, 199 F.R.D. 425, 435-36 (2001). Copies of Rule 5.2, dealing with service, and Rules 7.4 and 7.5, regarding "tag-along" actions, are attached for your convenience.

Inasmuch as there is an unavoidable time lag between notification of the pendency of the tag-along action and the filing of a conditional transfer order, counsel are required by Rule 7.4(b) to notify this office **BY FACSIMILE**, at (202) 502-2888, of any official changes in the status of the tag-along action. These changes could involve dismissal of the action, remand to state court, transfer to another federal court, etc., as indicated by an order filed by the district court. Your cooperation would be appreciated.

NOTICE OF OPPOSITION DUE ON OR BEFORE: July 18, 2008 (12 noon EST)
(Facsimile transmission is suggested.)

If you are considering opposing this conditional transfer order, please review Rules 7.4 and 7.5 of the Panel Rules before filing your Notice of Opposition.

A list of involved counsel is attached.

Very truly,

Jeffery N. Lüthi
Clerk of the Panel

By Tanisha Spinner
Tanisha Spinner
Deputy Clerk

Attachments

JUL 07 2008

JPML Form 39

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: HEPARIN PRODUCTS LIABILITY LITIGATION

MDL No. 1953

(SEE ATTACHED SCHEDULE)

CONDITIONAL TRANSFER ORDER (CTO-2)

On June 6, 2008, the Panel transferred two civil actions to the United States District Court for the Northern District of Ohio for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. *See* ____F.Supp.2d____ (J.P.M.L. 2008). With the consent of that court, all such actions have been assigned to the Honorable James G. Carr.

It appears that the actions on this conditional transfer order involve questions of fact that are common to the actions previously transferred to the Northern District of Ohio and assigned to Judge Carr.

Pursuant to Rule 7.4 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, 199 F.R.D. 425, 435-36 (2001), these actions are transferred under 28 U.S.C. § 1407 to the Northern District of Ohio for the reasons stated in the order of June 6, 2008, and, with the consent of that court, assigned to the Honorable James G. Carr.

This order does not become effective until it is filed in the Office of the Clerk of the United States District Court for the Northern District of Ohio. The transmittal of this order to said Clerk shall be stayed 15 days from the entry thereof. If any party files a notice of opposition with the Clerk of the Panel within this 15-day period, the stay will be continued until further order of the Panel.

FOR THE PANEL:

Jeffery N. Lüthi
Clerk of the Panel

IN RE: HEPARIN PRODUCTS LIABILITY LITIGATION

MDL No. 1953

SCHEDULE CTO-2 - TAG-ALONG ACTIONS

DIST. DIV. C.A. #	CASE CAPTION
FLORIDA SOUTHERN	
FLS 1 08-21540	Raul R. Cuadrado v. Baxter International, Inc.
GEORGIA NORTHERN	
GAN 1 08-1833	Bradley Gordon v. Baxter Healthcare Corp., et al.
ILLINOIS NORTHERN	
ILN 1 08-3329	Paul Hills v. Baxter Healthcare Corp., et al.
PENNSYLVANIA WESTERN	
PAW 2 08-741	Edith Kwitowski, etc. v. Baxter Healthcare Corp., et al.
TEXAS EASTERN	
TXE 9 08-82	Earl A. Grant v. Baxter Healthcare Corp.

RULE 7.4: CONDITIONAL TRANSFER ORDERS FOR "TAG-ALONG ACTIONS"

(a) Upon learning of the pendency of a potential "tag-along action," as defined in Rule 1.1 of these Rules, an order may be entered by the Clerk of the Panel transferring that action to the previously designated transferee district court on the basis of the prior hearing session(s) and for the reasons expressed in previous opinions and orders of the Panel in the litigation. The Clerk of the Panel shall serve this order on each party to the litigation but, in order to afford all parties the opportunity to oppose transfer, shall not send the order to the clerk of the transferee district court for fifteen days from the entry thereof.

(b) Parties to an action subject to a conditional transfer order shall notify the Clerk of the Panel within the fifteen-day period if that action is no longer pending in its transferor district court.

(c) Any party opposing the transfer shall file a notice of opposition with the Clerk of the Panel within the fifteen-day period. If a notice of opposition is received by the Clerk of the Panel within this fifteen-day period, the Clerk of the Panel shall not transmit said order to the clerk of the transferee district court until further order of the Panel. The Clerk of the Panel shall notify the parties of the briefing schedule.

(d) Within fifteen days of the filing of its notice of opposition, the party opposing transfer shall file a motion to vacate the conditional transfer order and brief in support thereof. The Chairman of the Panel shall set the motion for the next appropriate hearing session of the Panel. Failure to file and serve a motion and brief shall be treated as withdrawal of the opposition and the Clerk of the Panel shall forthwith transmit the order to the clerk of the transferee district court.

(e) Conditional transfer orders do not become effective unless and until they are filed with the clerk of the transferee district court.

(f) Notices of opposition and motions to vacate such orders of the Panel and responses thereto shall be governed by Rules 5.12, 5.2, 7.1 and 7.2 of these Rules.

RULE 7.5: MISCELLANEOUS PROVISIONS CONCERNING "TAG-ALONG ACTIONS"

(a) Potential "tag-along actions" filed in the transferee district require no action on the part of the Panel and requests for assignment of such actions to the Section 1407 transferee judge should be made in accordance with local rules for the assignment of related actions.

(b) Upon learning of the pendency of a potential "tag-along action" and having reasonable anticipation of opposition to transfer of that action, the Panel may direct the Clerk of the Panel to file a show cause order, in accordance with Rule 7.3 of these Rules, instead of a conditional transfer order.

(c) Failure to serve one or more of the defendants in a potential "tag-along action" with the complaint and summons as required by Rule 4 of the Federal Rules of Civil Procedure does not preclude transfer of such action under Section 1407. Such failure, however, may be submitted by such a defendant as a basis for opposing the proposed transfer if prejudice can be shown. The inability of the Clerk of the Panel to serve a conditional transfer order on all plaintiffs or defendants or their counsel shall not render the transfer of the action void but can be submitted by such a party as a basis for moving to remand as to such party if prejudice can be shown.

(d) A civil action apparently involving common questions of fact with actions under consideration by the Panel for transfer under Section 1407, which was either not included in a motion under Rule 7.2 of these Rules, or was included in such a motion that was filed too late to be included in the initial hearing session, will ordinarily be treated by the Panel as a potential "tag-along action."

(e) Any party or counsel in actions previously transferred under Section 1407 or under consideration by the Panel for transfer under Section 1407 shall promptly notify the Clerk of the Panel of any potential "tag-along actions" in which that party is also named or in which that counsel appears.

RULE 5.2: SERVICE OF PAPERS FILED

(a) All papers filed with the Clerk of the Panel shall be accompanied by proof of previous or simultaneous service on all other parties in all actions involved in the litigation. Service and proof of service shall be made as provided in Rules 5 and 6 of the Federal Rules of Civil Procedure. The proof of service shall indicate the name and complete address of each person served and shall indicate the party represented by each. If a party is not represented by counsel, the proof of service shall indicate the name of the party and the party's last known address. The proof of service shall indicate why any person named as a party in a constituent complaint was not served with the Section 1407 pleading. The original proof of service shall be filed with the Clerk of the Panel and copies thereof shall be sent to each person included within the proof of service. After the "Panel Service List" described in subsection (d) of this Rule has been received from the Clerk of the Panel, the "Panel Service List" shall be utilized for service of responses to motions and all other filings. In such instances, the "Panel Service List" shall be attached to the proof of service and shall be supplemented in the proof of service in the event of the presence of additional parties or subsequent corrections relating to any party, counsel or address already on the "Panel Service List."

(b) The proof of service pertaining to motions for transfer of actions pursuant to 28 U.S.C. §1407 shall certify that copies of the motions have been mailed or otherwise delivered for filing to the clerk of each district court in which an action is pending that will be affected by the motion. The proof of service pertaining to a motion for remand pursuant to 28 U.S.C. §1407 shall certify that a copy of the motion has been mailed or otherwise delivered for filing to the clerk of the Section 1407 transferee district court in which any action affected by the motion is pending.

(c) Within eleven days of filing of a motion to transfer, an order to show cause or a conditional transfer order, each party or designated attorney shall notify the Clerk of the Panel, in writing, of the name and address of the attorney designated to receive service of all pleadings, notices, orders and other papers relating to practice before the Judicial Panel on Multidistrict Litigation. Only one attorney shall be designated for each party. Any party not represented by counsel shall be served by mailing such pleadings to the party's last known address. Requests for an extension of time to file the designation of attorney shall not be granted except in extraordinary circumstances.

(d) In order to facilitate compliance with subsection (a) of this Rule, the Clerk of the Panel shall prepare and serve on all counsel and parties not represented by counsel, a "Panel Service List" containing the names and addresses of the designated attorneys and the party or parties they represent in the actions under consideration by the Panel and the names and addresses of the parties not represented by counsel in the actions under consideration by the Panel. After the "Panel Service List" has been received from the Clerk of the Panel, notice of subsequent corrections relating to any party, counsel or address on the "Panel Service List" shall be served on all other parties in all actions involved in the litigation.

(e) If following transfer of any group of multidistrict litigation, the transferee district court appoints liaison counsel, this Rule shall be satisfied by serving each party in each affected action and all liaison counsel. Liaison counsel designated by the transferee district court shall receive copies of all Panel orders concerning their particular litigation and shall be responsible for distribution to the parties for whom he or she serves as liaison counsel.

IN RE: HEPARIN PRODUCTS LIABILITY LITIGATION

MDL No. 1953

INVOLVED COUNSEL LIST (CTO-2)

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EXHIBIT C

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	James F. Holderman	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	08 C 2168	**DATE**	7/1/2008
CASE TITLE	Arnold vs. Baxter Healthcare Corp.		

DOCKET ENTRY TEXT

For the reasons set forth in the Statement portion of this order, defendant Baxter Healthcare Corporation's Motion for Stay of Proceedings Pending Transfer to the Judicial Panel on Multidistrict Litigation [6] is granted and Plaintiffs' Motion to Remand [15] is continued.

■[For further details see text below.] Notices mailed.

STATEMENT

On March 8, 2008, plaintiffs Patrick Arnold and Elizabeth Arnold ("Plaintiffs") filed a four-count Complaint against Baxter Healthcare Corporation ("Baxter") in the Circuit Court of Cook County, claiming strict liability, negligence, and loss of consortium due to damages caused when the drug heparin — manufactured, supplied, and distributed by Baxter — was administered to Patrick Arnold on January 16, 2008. On April 16, 2008, Baxter removed the case to federal court, arguing that the necessary interpretation of federal regulations related to the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 ("FDCA"), raises a substantial question of federal law, thereby conferring federal-question jurisdiction pursuant to 28 U.S.C. § 1331. Plaintiffs then filed a Motion to Remand, (Dkt. No. 15), contending that this court lacks jurisdiction over their state law claims.

At the same time this litigation was beginning, the plaintiffs in a separate heparin-related class action lawsuit filed a motion pursuant to 28 U.S.C. § 1407 to consolidate over a dozen cases alleging injuries caused by heparin supplied and sold by Baxter. On June 6, 2008, the United States Judicial Panel on Multidistrict Litigation (the "Panel") granted the motion, assigning the heparin cases to the United States District Court for the Northern District of Ohio for consolidated pretrial proceedings. Then, on June 17, 2008, the Panel issued a conditional transfer order notifying the parties in this case that it is scheduled to be transferred to the Northern District of Ohio on July 2, 2008 as part of the consolidated proceedings. Plaintiffs have requested a ruling on their now fully-briefed Motion to Remand before the conditional transfer order goes into effect. (Dkt. No. 27; *see also* Rule 1.5, *Rules of Procedure of the Judicial Panel on Multidistrict Litigation* ("The pendency of a . . . conditional transfer order . . . before the Panel concerning transfer or remand of an action pursuant to 28 U.S.C. § 1407 does not affect or suspend orders and pretrial proceedings in the district court in which the action is pending and does not in any way limit the pretrial jurisdiction of that court.").) Baxter has filed a Motion for Stay of Proceedings Pending Transfer to the Judicial Panel on Multidistrict Litigation, (Dkt. No. 6), which remains pending before this court.

STATEMENT

The first question this court must decide is whether Plaintiffs' Motion to Remand should be decided before the case is transferred to the MDL court. The answer to this question is determined by a three-part test first set forth by the court in *Meyers v. Bayer AG*, 143 F. Supp. 2d 1044 (E.D. Wis. 2001); *see Alegre v. Aguayo*, No. 06 C 5744, 2007 WL 141891, at *2 (N.D. Ill. Jan. 17, 2007); *Nauheim v. The Interpublic Group of Cos.*, No. 02-C-9211, 2003 WL 1888843, at *2 (N.D. Ill. Apr. 16, 2003); *Bd. of Tr. of Teachers' Ret. Sys. v. Worldcom, Inc.*, 244 F. Supp. 2d 900, 902-05 (N.D. Ill. 2002). First, the court makes a preliminary determination on the merits of the motion to remand. *Meyers*, 143 F. Supp. 2d at 1049. "If this preliminary assessment suggests that removal was improper, the court should promptly complete its consideration and remand the case to state court." *Id.* On the other hand, if the jurisdictional issue is factually or legally difficult, the court must determine whether identical or similar jurisdictional issues have been raised in other cases that are part of the MDL proceeding. *Id.* Where a difficult jurisdictional question is shared by other cases in the MDL proceeding, the court should consider staying the proceedings so the jurisdictional questions can be resolved together by the MDL court. *Id.*

District courts have federal-question jurisdiction over all actions "arising under" federal law. *See* 28 U.S.C. § 1331. In cases asserting only state law claims, such as this one, the lawsuit can still arise under federal law if "some substantial, disputed question of federal law is a necessary element of one of the well-pleaded state claims." *Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 13 (1983). In *Merrell Dow Pharmaceuticals Inc. v. Thompson*, the Supreme Court addressed the specific question of whether "the incorporation of a federal standard in a state-law private action, when Congress has intended that there not be a federal private action for violations of that federal standard, makes the action one 'arising under the Constitution, laws, or treaties of the United States.'" *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 805 (1986). The *Merrell Dow* Court held that it did not. In that case, the plaintiffs had alleged a negligence claim based on "misbranding" in violation of the FDCA. The Court first assumed that there is no federal private cause of action for FDCA violations and then concluded that "the congressional determination that there should be no federal remedy for the violation of this federal statute is tantamount to a congressional conclusion that the presence of a claimed violation of the statute as an element of a state cause of action is insufficiently 'substantial' to confer federal-question jurisdiction." *Id.* at 814.

In this case, Plaintiffs have alleged, *inter alia*, that Baxter was negligent for "[f]ail[ing] to comply with all statutes, laws, regulations, and safety codes pertaining to the manufacture, production, distribution, storage, and sale of heparin," and for "fail[ing] to exercise care in acquiring the ingredients for heparin only from producers and suppliers that had undergone proper inspection and evaluation, including, but not limited to, inspection and evaluation by the [Food and Drug Administration]." (Compl. Count II, ¶¶ 7(d) & (i).) Baxter contends that these claims raise a substantial question of federal law in that they "directly challenge the FDA's approval and regulation of heparin and the federal regulatory process governing the approval and sale of prescription drugs." (Dkt. No. 26 at 2.) Baxter further argues that "this lawsuit will require a determination that specific aspects of the federal regulatory process governing prescription drugs are insufficient to protect the public health." (*Id.* at 3.)

In *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, the Supreme Court noted its concern in *Merrell Dow* that "exercising federal jurisdiction over a state misbranding action would have attracted a horde of original filings and removal cases raising other state claims with embedded federal issues." *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 318 (2005). At the same time, however, the Court recognized that "a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Id.* at 312. Both *Grable* and *Merrell Dow* caution against "a potentially enormous shift of traditionally state cases into federal

STATEMENT

courts." *Grable*, 545 U.S. at 319. Ultimately, however, they also stress "the need for careful judgments about the exercise of federal judicial power in an area of uncertain jurisdiction." *Merrell Dow*, 478 U.S. at 814.

In this case, it appears that the FDA was heavily involved in approving the manufacturing, distribution, and sale of heparin. If Baxter in fact complied with all federal regulations, but was still found negligent under Illinois state law, this finding would necessarily implicate both the actions of the FDA and the efficacy of the applicable FDCA regulations. With these aspects of the case in mind, the court finds the jurisdictional question at issue to be fairly complex. Baxter informs the court that there are "at least four other heparin cases that have been removed to federal court based, at least in part, on federal question jurisdiction." (Dkt. No. 26 at 2.) Because the jurisdictional question in this case warrants a careful analysis of the "congressionally approved balance of federal and state judicial responsibilities," *Grable*, 545 U.S. at 314, this court declines to rule on Plaintiffs' Motion to Remand at this time, deferring a determination on the merits so that the MDL court can uniformly treat this question in all similar cases pending before it.

The court understands from Patrick Arnold's affidavit, (Dkt. No. 22, Ex. A), that he is in delicate health. However, the court does not perceive that its granting of Baxter's motion for stay of proceedings will unduly prejudice Plaintiffs, as the MDL court must address the jurisdictional question as a threshold matter. *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 94-95 (1998). The judicial economy to be saved in granting the motion for stay outweighs any sleight delay in the resolution of this important question.

Baxter's Motion for Stay of Proceedings Pending Transfer to the Judicial Panel on Multidistrict Litigation is accordingly granted and Plaintiffs' Motion to Remand is continued.

EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ROME DIVISION

Nancy Ann Fowler,
et al.,

Plaintiffs,

v. CIVIL ACTION FILE
NO. 4:08-CV-0055-HLM

Hamilton Medical Center, Inc.,
et al.,

Defendants.

ORDER

This case is before the Court on Defendant Baxter Healthcare Corporation's Motion to Stay Proceedings Pending Transfer to the Judicial Panel on Multidistrict Litigation ("Motion to Stay") [11].

I. Background

Defendant Baxter Healthcare Corporation ("Defendant Baxter") has moved to stay all of the proceedings in this

case pending a decision by the Judicial Panel on Multidistrict Litigation ("JPML") on various motions to transfer filed in this case and in related cases. Defendant Baxter argues that pretrial discovery in the cases will overlap, that consolidation in one transferee court is appropriate, and that staying the proceedings in this case will further the interests of judicial economy and efficiency by eliminating unnecessary duplication of litigation. Defendant Baxter further contends that if the Court refuses to stay the proceedings in this case, Defendant Baxter will be placed in the position of having to develop and present similar defenses in separate federal district courts.

The other Defendants in this litigation apparently oppose the Motion to Stay, and instead argue that an Order remanding this case to the Superior Court of Whitfield

County, Georgia, is appropriate. As of the date of this Order, Plaintiffs have not responded to Defendant Baxter's Motion, and the time for doing so has expired.[1]

II. Discussion

28 U.S.C.A. § 1407 permits the transfer of cases pending in different districts that involve common questions of fact to the same district for coordinated or consolidated

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[1]The Court directs counsel to comply with the provisions of the Local Rules governing reply briefs, amended briefs, and surreply briefs. Specifically, counsel ordinarily must obtain permission from the Court prior to filing an amended brief or a surreply brief. The Court will direct the Clerk to strike all future briefs filed by the parties that do not comply with this rule, and will require the parties to re-file those briefs after obtaining permission from the Court to file the briefs.

The Court also refers counsel to the response time requirements set forth in the Local Rules. Ordinarily, parties must respond to Motions, other than summary judgment motions, within ten business days, plus three days for mailing. By the Court's calculation, the Georgia Defendants' response to Defendant Baxter's Motion to Stay, and Plaintiffs' response to that Motion, were due on May 6, 2008, not May 1, 2008, as Defendant Baxter asserts.

pretrial proceedings. 28 U.S.C.A. § 1407(a).[2] "A pending motion before the JPML does not affect the jurisdiction of the transferor court." Falgoust v. Microsoft Corp., No. CIV.A. 00-0779, 2000 WL 462919, at *1 (E.D. La. Apr. 19, 2000).[3]

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[2]28 U.S.C.A. § 1407(a) provides:

> When civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings. Such transfers shall be made by the judicial panel on multidistrict litigation authorized by this section upon its determination that transfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions. Each action so transferred shall be remanded by the panel at or before the conclusion of such pretrial proceedings to the district from which it was transferred unless it shall have been previously terminated: Provided, however, That the panel may separate any claim, cross-claim, counter-claim, or third-party claim and remand any of such claims before the remainder of the action is remanded.

28 U.S.C.A. § 1407(a).

[3]Indeed, Rule 1.5 of the Rules of Procedure of the JPML

A court, however, has "inherent power to 'control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants.'" Id. (quoting Landis v. N. Am. Co., 299 U.S. 248, 254 (1936)). Consequently, the Court has discretion to grant a stay of proceedings in this case pending the JPML's decision on the pending motions to transfer. McCrary v.

---

states:

> The pendency of a motion, order to show cause, conditional transfer order or conditional remand order before the Panel concerning transfer or remand of an action pursuant to 28 U.S.C. § 1407 does not affect or suspend orders and pretrial proceedings in the district court in which the action is pending and does not in any way limit the pretrial jurisdiction of that court. A transfer or remand pursuant to 28 U.S.C. § 1407 shall be effective when the transfer or remand order is filed in the office of the clerk of the district court of the transferee district.

J.P.M.L. R. 1.5.

Bayer Corp., No. CIV.A. 02-642, 2002 WL 1467691, at *1 (E.D. La. July 3, 2002). Indeed, courts frequently grant stays pending transfer decisions by the JPML to avoid duplicative efforts and to promote judicial economy. Smith v. Mail Boxes, Etc. USA, Inc., 191 F. Supp. 2d 1155, 1157 (E.D. Cal. 2002) (collecting cases); Tench v. Jackson Nat'l Life Ins. Co., No. 99 C 5182, 1999 WL 1044923, at *1 (N.D. Ill. Nov. 12, 1999). "When considering a motion to stay, the district court should consider three factors: (1) potential prejudice to the non-moving party; (2) hardship and inequity to the moving party if the action is not stayed; and (3) the judicial resources that would be saved by avoiding duplicative litigation if the cases are in fact consolidated." Rivers v. Walt Disney Co., 980 F. Supp. 1358, 1360 (C.D. Cal. 1997).

For the following reasons, the Court finds that staying this action pending the JPML's decision on the motions to transfer is appropriate. First, the JPML has scheduled a hearing on the motions to transfer for May 29, 2008, and, based on the Court's own experience with the JPML, the JPML likely will rule on the pending motions to transfer within the next two to three months. Plaintiffs and the remaining Defendants will suffer little, if any, prejudice from such a short stay.

Second, Defendant Baxter will suffer prejudice and hardship if the Court does not grant a stay in this action. If the Court does not grant a stay, Defendant Baxter will be required to develop and to present similar defenses in several district courts, and will have to engage in duplicate briefing of motions and potentially duplicative discovery.

Third, staying the proceedings in this case will promote judicial economy and efficiency. If the JPML ultimately transfers this case to another district court, the Court will have needlessly expended its energies and resources to familiarize itself with this case. Rivers, 980 F. Supp. at 1360. Further, any efforts that this Court might make with respect to case management and discovery "will most likely have to be replicated by the judge [who] is assigned to handle the consolidated litigation if the [JPML] does not consolidate the [Heparin] cases in this Court." Id. at 1361. Additionally, the transferee court may well be in a better position to address the other motions that remain pending in this case, such as the Joint Motion to Remand. Under those circumstances, granting a stay will conserve judicial resources.

For the above reasons, the Court finds that staying the proceedings in this case pending the JPML's decisions on the pending motions to transfer, is appropriate. The Court therefore grants Defendant Baxter's Motion to Stay.

III. Conclusion

ACCORDINGLY, the Court **GRANTS** Defendant Baxter Healthcare Corporation's Motion to Stay Proceedings Pending Transfer to the Judicial Panel on Multidistrict Litigation [11], and **STAYS** the proceedings in this case pending the JPML's decision on the pending motions to transfer. The Court **DEFERS** ruling on all of the other pending Motions in this case pending a decision by the JPML concerning the Motion to Transfer, including: (1) the Motion to Dismiss filed by Defendants Hamilton Health Care System, Inc. and Hamilton Medical Center, Inc. [3]; (2) the

Motion to Dismiss filed by Defendants Maxwell and N.W. Georgia Hematology and Oncology, P.C. [5]; (3) Plaintiffs' Motion Requesting the Court to Toll Time for the Filing by Plaintiffs of a Medical Malpractice Affidavit [8]; (4) the Joint Motion to Remand to State Court [12]; and (5) Plaintiffs' Motion to Dismiss John C. Church and Dalton Imaging Center [14].

IT IS SO ORDERED, this the 7th day of May, 2008.

UNITED STATES DISTRICT JUDGE

EXHIBIT E

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Robert W. Gettleman	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	08 C 2058	**DATE**	6/23/2008
CASE TITLE	Mark Andrew Scott vs Baxter International, Inc., et al		

DOCKET ENTRY TEXT:

Pursuant to the conditional transfer order, (CTO-1), this action is transferred under 28 U.S.C. §1407 to the Northern District of Ohio, MDL Docket No.1953 in re: Heparin Products Liability Litigation.

[Docketing to mail notice]

Courtroom Deputy Initials:	GDS